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MAR 16 2010

AT 8:30
WILLIAM T. WALSH
CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,)	
Plaintiff)	Civ. No. 09-cv-3211-JAG-ES
v.)	CONSENT DECREE OF PERMANENT INJUNCTION
QUALITY FORMULATION LABORATORIES, INC., and AMERICAN SPORTS NUTRITION, INC., corporations, SPORTS NUTRITION INTERNATIONAL, LLC, a limited liability company, and MOHAMED S. DESOKY, an individual,)	
Defendants.)	

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunctive Relief against Quality Formulation Laboratories, Inc., and American Sports Nutrition, Inc., corporations, Sports Nutrition International, LLC, a limited liability company, and Mohamed S. Desoky, an individual (collectively "Defendants"), and the Defendants having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

I. This Court has jurisdiction over the subject matter and over all parties to this action.

II. The Complaint for Injunction states a claim for relief against the Defendants under the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 301 et seq.

III. The Complaint alleges that the Defendants violate the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) or (c).

IV. The Complaint alleges that the Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) or (c) while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

V. The Complaint alleges that the Defendants violate the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are misbranded within the meaning of 21 U.S.C. § 343(w), (i)(2), or (r)(1)(A).

VI. The Complaint alleges that the Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food to be misbranded within the meaning of 21 U.S.C. § 343(w), (i)(2), or

(r)(1)(A) while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

VII. Upon entry of this Decree, the Defendants and each and all of their officers, agents, employees, successors, and assigns, and any persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly receiving, manufacturing, preparing, packing, labeling, and distributing at their plant located at 110 Pennsylvania Avenue, Paterson, New Jersey, or its other street addresses, 51 Kentucky Avenue and 78 Iowa Avenue (and any other location(s) or any new location(s) at which the Defendants receive, manufacture, prepare, pack, label, hold, or distribute articles of food), any article of food unless and until the following conditions have been met:

A. The Defendants select an expert or experts (the "sanitation expert") having no personal or financial ties (other than a consulting agreement) to the Defendants or the Defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop and implement a written sanitation control program that will assure the Defendants' compliance with Current Good Manufacturing Practice ("cGMP") and that will protect food, food-contact surfaces, and food-packaging materials from contamination from any source, including but not limited to filth, and from cross-contaminated with food allergens, and:

1. The Defendants inform the United States Food and Drug Administration ("FDA") in writing of the name and qualifications of the sanitation expert as soon as they retain the expert;

2. The sanitation expert develops a written sanitation control program for manufacturing, preparing, packing, holding, and distributing the Defendants' articles of food,

as described in paragraph VII.A., and such plan is submitted to FDA within ten (10) business days of the entry of this Decree;

3. The Defendants receive written notification from FDA approving the sanitation control program developed by the sanitation expert. After the sanitation control program is submitted to FDA as directed in paragraph VII.A.2, FDA will review the sanitation control program as soon as reasonably practicable, taking into consideration FDA's resource constraints and other responsibilities. If the sanitation control program cannot be approved as submitted, FDA will provide the Defendants with a written explanation of the plan's deficiencies and will review any corrected, amended, or modified sanitation control program in the manner described in this paragraph;

4. The Defendants make the sanitation control program available and accessible to all their employees and will as soon as reasonably practical make the sanitation program available in Spanish or any other language(s) so that it is understood by all employees;

5. The sanitation expert develops a written employee training program that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and the sanitation expert provides the training to management and management trains each line employee. Defendants will document that each employee received and understood such training;

6. The Defendants assign the responsibility and authority for implementing and monitoring the sanitation control program on a continuing basis to an employee who is trained in sanitation control requirements and qualified to implement and monitor the sanitation control program;

7. The sanitation expert inspects the Defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records

contained therein, to determine whether the Defendants have adequately established and implemented the FDA-approved sanitation control program, whether the Defendants have adequately addressed the FDA investigators' inspectional observations listed on each Form FDA-483 issued to the Defendants since January 2007, and whether the Defendants comply with cGMP and the Act; and

8. Within five (5) business days of FDA's approval of the sanitation control program pursuant to paragraph VII.A.3, the sanitation expert certifies to FDA in writing that the Defendants have adequately established and implemented the FDA-approved sanitation control program, have adequately addressed the Form FDA-483 observations, and comply with cGMP and the Act and, as part of the certification, provides to FDA a written report describing in detail the actions the Defendants have taken to ensure that, on an ongoing basis, they adequately implement the FDA-approved sanitation control program and comply with cGMP and the Act. The sanitation expert may choose to conduct separate inspections (pursuant to paragraph VII.A.7) and provide separate certifications and certification reports for the Defendants' products formulated to contain milk, whey, casein, or any other ingredient with milk proteins and for the Defendants' products that are not formulated to contain any of these ingredients so long as each certification and accompanying report includes all of the controls applicable for protecting the products that are the subject of the certification, as well as the food-contact surfaces and food-packaging materials, from contamination from any source, and;

B. The Defendants select an expert or experts (the "labeling expert") having no personal or financial ties (other than a consulting agreement) to the Defendants or the Defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to determine whether the Defendants' finished product and bulk

finished product labeling complies with 21 U.S.C. §§ 342(c) and 343 and applicable regulations, and:

1. The Defendants inform FDA in writing of the name and qualifications of the labeling expert as soon as they retain such expert;
2. The labeling expert performs a review of all of the Defendants' finished product and bulk finished product labeling to determine whether the labeling complies with 21 U.S.C. §§ 342(c) and 343 and applicable regulations; and
3. Within five (5) business days of completing the review of the Defendants' labeling, the labeling expert certifies to FDA in writing that all of the Defendants' finished product and bulk finished product labeling complies with 21 U.S.C. §§ 342(c) and 343 and applicable regulations and, as part of the certification, provides to FDA copies of all of the Defendants' labeling, along with corresponding product formulation records, reviewed pursuant to paragraph VII.B.2. and a written report describing in detail the actions the Defendants have taken to ensure that, on an ongoing basis, their finished product and bulk finished product labeling will comply with 21 U.S.C. §§ 342(c) and 343 and applicable regulations;
4. After the labeling expert's certification along with copies of the Defendants' labeling and corresponding product formulation records are submitted to FDA as directed in paragraph VII.B.3, FDA will review the labeling as soon as reasonably practicable, taking into consideration FDA's resource constraints and other responsibilities. FDA will provide the Defendants with a written explanation of FDA's claimed labeling deficiencies, if any, and will review any corrected, amended, or modified labeling, as necessary, in the manner described in this paragraph;

C. With respect to all raw ingredients, in-process and finished articles of food, and finished product and bulk finished product labeling that are located at the Defendants' plant,

or are elsewhere within the Defendants' possession, custody, or control, the Defendants meet the following requirements:

1. Under the supervision of the sanitation expert retained pursuant to paragraph VII.A., and under FDA supervision as FDA deems necessary, the Defendants destroy all in-process and finished articles of food that FDA deems adulterated under the Act;
2. Under the supervision of the sanitation expert retained pursuant to paragraph VII.A., and under FDA supervision as FDA deems necessary, the Defendants destroy all raw ingredients stored under conditions that indicate that they may be contaminated with filth (e.g., rodent gnawing or urine stains on bags of food, rodent excreta pellets in, on, under, or around bags of food); and
3. Under the supervision of the labeling expert retained pursuant to paragraph VII.B., and under FDA supervision as FDA deems necessary, the Defendants destroy all labeling for finished products and bulk finished products that does not comply with 21 U.S.C. §§ 342(c) and 343 and applicable regulations;

D. The Defendants recall all articles of food, as FDA deems necessary, that have been distributed to consumers or are within the possession, custody, or control of the Defendants' distributors, agents, or customers. Defendants may petition the Court to stay or block such a recall;

E. FDA, as it deems necessary to evaluate the Defendants' compliance with the terms of paragraph VII of this Decree, conducts inspections of the Defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, articles of food, finished product and bulk finished product labeling, and relevant records contained therein, and collects and analyzes samples of the Defendants' articles of food. Any inspection(s) conducted pursuant to this paragraph will be conducted as soon as reasonably practicable, taking into consideration

FDA's resource constraints and other responsibilities, after FDA's receipt of the sanitation expert's certification pursuant to paragraph VII.A.8;

F. The Defendants pay the costs of any supervision, inspection, analyses, examination, and review that FDA deems necessary to evaluate the Defendants' compliance with the terms of paragraph VII.; and

G. The Defendants receive written notification from FDA stating that the Defendants appear to be in compliance with the requirements set forth in paragraphs VII.A. through F., cGMP, and the Act, and authorizing the Defendants to resume receiving, manufacturing, preparing, packing, labeling, and distributing articles of food. If the sanitation expert has provided a certification and certification report limited pursuant to paragraph VII.A.8 to products formulated to contain milk, whey, casein, or any other ingredient with milk proteins, and the Defendants have met all other requirements set forth in paragraphs VII.A through F., cGMP, and the Act, then FDA, as it deems appropriate, may issue the notification under this paragraph to authorize a partial resumption of manufacturing and distribution of specified products.

VIII. Upon resuming operations after completing the requirements in paragraph VII., the Defendants shall meet the following requirements:

A. The Defendants shall notify FDA in writing of any change in the identity or quantity of any raw ingredient in any batch formulation or any change in manufacturing instructions for any of their articles of food, at least ten (10) calendar days before implementing any such change;

B. For each new product or new bulk finished product, the Defendants shall retain the labeling expert described in paragraph VII.B. (or a similarly qualified expert, provided that the Defendants inform FDA in writing of the name and qualifications of the expert as soon

as the expert is retained) and have the expert conduct the following actions prior to the Defendants' first use of the new product labeling or new bulk finished product labeling:

1. Perform a review of the Defendants' new labeling to ensure compliance with 21 U.S.C. §§ 342(c) and 343 and applicable regulations; and
2. Certify to FDA in writing whether the Defendants' new labeling complies with 21 U.S.C. §§ 342(c) and 343 and applicable regulations;

C. The Defendants select a laboratory that, by reason of background, staff training, and experience, is qualified to analyze articles of food to determine whether the food contains ingredients not listed or declared on its labeling or substances not intended to be present in the food, and the Defendants inform FDA in writing of the laboratory's name and qualifications as soon as they retain the laboratory;

D. For a minimum of one (1) year from the date of receipt of FDA's written notification described in paragraph VII.G., and for *each batch (or lot) of each flavor of each product* that does not list on its labeling, milk, whey, casein, or any other ingredient containing milk proteins, the Defendants shall:

1. Provide the laboratory described in paragraph VIII.C. with product samples described in paragraph VIII.D., and corresponding product labeling;
2. For each sample, provide to FDA a copy of the labeling submitted to the laboratory and a sampling report documenting, at a minimum, the date and time of sampling, the lot number sampled, the type of product sampled, the sampling method used, and the name of the person doing the sampling;
3. Obtain laboratory analyses of the samples for the presence of milk proteins; and

4. Have the laboratory simultaneously provide to FDA and the Defendants all results of the analyses;

E. Except as otherwise specified in paragraph VIII.E.4., at least once every three (3) months for a minimum of one (1) year from the date of receipt of FDA's written notification described in paragraph VII.G., and thereafter at least twice each year for a minimum of two (2) years, or longer as and when FDA deems necessary, the Defendants shall retain the sanitation expert described in paragraph VII.A. (or a similarly qualified expert, provided that the Defendants inform FDA in writing of the name and qualifications of the expert as soon as the expert is retained) to:

1. Inspect the Defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein;

2. Notify FDA by telephone of the any potential deficiency or noncompliance by Defendants, within twenty-four (24) hours after the expert became aware of such potential deficiency or noncompliance, and if, during the inspection, the expert becomes aware that the Defendants do not adequately implement the FDA-approved sanitation control program or do not comply with cGMP or the Act;

3. Within thirty (30) calendar days after commencing any inspection under Paragraph VII.E, certify to FDA in writing whether the Defendants are adequately implementing the FDA-approved sanitation control program and are complying with cGMP and the Act, and provide to FDA a written report describing in detail the deviations, if any, from the FDA-approved sanitation control program, cGMP, or the Act and identifying the corrective measures that the Defendants have taken, and plan to take, to ensure that they are operating in compliance with the Decree, cGMP, and the Act;

4. Select and collect samples of *one batch (or lot) of each of the Defendants' products* that do not list on their labeling, milk, whey, casein, or any other ingredient containing milk proteins, at least twice every year for a minimum of two (2) years, or longer as and when FDA deems necessary, for the time period beginning at the end of the first year from the date of receipt of FDA's written notification described in paragraph VII.G.; and

5. For each sample, prepare a sampling report documenting, at a minimum, the date and time of sampling, the lot number sampled, the type of product sampled, the sampling method used, and the name of the person doing the sampling;

F. For the product samples collected pursuant to paragraph VIII.E.4., the Defendants shall:

1. Provide each sample and corresponding product labeling to the laboratory described in paragraph VIII.C. (or a similarly qualified laboratory, provided that the Defendants inform FDA in writing of the laboratory's name and qualifications as soon as the laboratory is retained);

2. For each sample, provide to FDA a copy of the labeling submitted to the laboratory and the sampling report prepared by the expert;

3. Obtain laboratory analyses of the samples for the presence of milk proteins; and

4. Have the laboratory simultaneously provide to FDA and the Defendants all results of the analyses; and

G. At least once every six (6) months for a minimum of one (1) year from the date of receipt of FDA's written notification described in paragraph VII.G., and thereafter at least once each year for a minimum of two (2) years, or longer as and when FDA deems necessary, the Defendants shall retain the labeling expert described in paragraph VII.B. (or a

similarly qualified expert, provided that the Defendants inform FDA in writing of the name and qualifications of the expert as soon as the expert is retained) to:

1. Perform a review of all of the Defendants' finished product and bulk finished product labeling; and
2. Within thirty (30) calendar days after commencing the review, certify to FDA in writing whether all of the Defendants' finished product and bulk finished product labeling complies with 21 U.S.C. §§ 342(c) and 343 and applicable regulations, and provide to FDA a written report describing in detail the deviations, if any, from 21 U.S.C. §§ 342(c) and 343 or applicable regulations and identifying the corrective measures that the Defendants have taken, and plan to take, to ensure that they are operating in compliance with 21 U.S.C. §§ 342(c) and 343 and applicable regulations.

IX. FDA shall be permitted, without prior notice and as and when it deems necessary, to make inspections of the Defendants' plant located at 110 Pennsylvania Avenue, Paterson, New Jersey (or its other street addresses, 51 Kentucky Avenue and 78 Iowa Avenue), and any other location(s) or any new location(s) at which the Defendants receive, manufacture, prepare, pack, label, hold, or distribute articles of food and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, FDA regulations, and the Act. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of the Defendants' raw ingredients, in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, manufacturing, preparing, packing, labeling, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree

and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

X. The Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate the Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: \$87.57 per hour and fraction thereof per representative for inspection work; \$104.96 per hour or fraction thereof per representative for analytical or review work; \$0.50 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

XI. The Defendants and each and all of their officers, agents, employees, successors, and assigns, and any persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. Violates the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) or (c);

B. Violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) or (c) while such articles are held for sale after shipment of one or more ingredients in interstate commerce;

C. Violates the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are misbranded within the meaning of 21 U.S.C. § 343(w), (i)(2), or (r)(1)(A);

D. Violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be misbranded within the meaning of 21 U.S.C. § 343(w), (i)(2), or (r)(1)(A) while such articles are held for sale after shipment of one or more ingredients in interstate commerce; or

E. Failing to implement and continuously maintain the requirements of this Decree.

XII. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, report, or other information, that the Defendants have failed to comply with any provision of this Decree, have violated cGMP or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, cGMP, or the Act, FDA may, as and when it deems necessary, issue a directive notifying the defendants in writing of the noncompliance and ordering the Defendants to take appropriate action, including but not limited to ordering the Defendants immediately to take one or more of the following actions:

A. Cease receiving, manufacturing, preparing, packing, labeling, holding, and distributing articles of food until the defendants receive written notification from FDA that the Defendants appear to be in compliance with the Decree, cGMP, and the Act, and that the Defendants may resume operations;

B. Recall any and all of the Defendants' articles of food that have been distributed to consumers or are within the possession, custody, or control of the Defendants' distributors, agents, or customers that are misbranded or adulterated;

C. Submit samples of the Defendants' articles of food to a qualified laboratory to determine the presence of any ingredient(s) or substance(s) that FDA in its discretion selects; and

D. Take any other corrective actions as FDA deems necessary to protect the public health or bring the defendants into compliance with this Decree, cGMP, and the Act, including but not limited to requiring that the defendants re-implement or re-institute any of the requirements of this Decree. The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA. The Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in paragraph X of this Decree.

XIII. Upon receipt of an FDA directive described in paragraph XII, the following procedures shall apply:

A. Unless a different time frame is specified by FDA in its directive, within ten (10) calendar days after receiving such directive, the Defendants shall notify FDA in writing either that:

(1) The Defendants are undertaking or have undertaken corrective action, in which event the Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or

(2) The Defendants do not agree with FDA's directive. If the Defendants notify FDA that they do not agree with FDA's directive, the Defendants shall explain in writing the basis for their disagreement. In so doing, the Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If the Defendants notify FDA that they do not agree with FDA's directive, FDA will review the Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its directive, as FDA deems appropriate. If FDA affirms or modifies its directive, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its directive, the Defendants shall, upon receipt of FDA's directive, immediately implement the directive (as modified, if applicable) and, if they so choose, bring the matter before this Court on an expedited basis. The Defendants shall continue to diligently comply with the terms of FDA's directive unless and until the Court modifies or overturns the directive. Any such judicial review shall be subject to the standard described in Paragraph XVIII of this Decree.

XIV. The Defendants shall provide notice of this Decree in the following manner:

A. Within ten (10) calendar days after entry of this Decree, the Defendants shall:

1. Provide a copy of this Decree, personally or, when necessary, by certified mail, return receipt requested, to each of their officers, agents, employees (who shall receive a copy of the Decree in English, Spanish, or other language as needed for the Decree to be understood), successors, and assigns, and any persons in active concert or participation with any of them;

2. Post a copy of this Decree in English, Spanish, and any other language(s) so that it is understood by all employees, on a bulletin board in the employee common area at the Defendants' plant, and shall ensure that the Decree remains posted so long as the Decree remains in effect; and

3. Hold a general meeting or series of smaller meetings for their employees, at which they shall describe the terms and obligations of this Decree;

B. Within twenty (20) calendar days after entry of this Decree, the Defendants shall provide FDA with an affidavit signed by the Defendants attesting to their compliance with paragraph XIV.A., stating the fact and manner of compliance, and identifying the names and positions of all persons who were notified under the requirements in paragraph XIV.A.; and

C. Within ten (10) calendar days after the date of employment of each new employee hired by the Defendants after the Defendants have complied with the provisions in paragraph XIV.A., the Defendants shall provide the new employee with a copy of the Decree (in English, Spanish, or other language as needed for the Decree to be understood), personally or, when necessary, by certified mail, return receipt requested.

XV. The Defendants shall notify FDA in writing at least thirty (30) calendar days before any change ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. The Defendants shall provide any prospective successor or assign with a copy of this Decree at least thirty (30) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within fifteen (15) calendar days after providing a copy of this Decree to a prospective successor or assign.

XVI. If any Defendant fails to comply with the provisions of this Decree, then the Defendants shall pay to the United States liquidated damages in the sum of twelve thousand dollars (\$12,000.00) for each day that the Defendant fails to comply with this Decree and an

additional fifteen thousand dollars (\$15,000.00) for each shipment of each finished product or bulk finished product that fails to comply with this Decree. The Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional civil or criminal penalties based on conduct that may also be the basis for payment of the liquidated damages. Defendants shall have ten (10) business days to either pay any amount demanded by FDA under this Paragraph or seek review of FDA's demand by the Court.

XVII. If any Defendant violates this Decree and is found in civil or criminal contempt, the Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

XVIII. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by a Court of any FDA decision rendered pursuant to this Decree shall be conducted without any discovery by either party and shall be based exclusively upon the written record that was before FDA at the time the decision was made.

XIX. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

XX. The Defendants shall address all communications with FDA required under this Decree to Director, New Jersey District Office, Food and Drug Administration, Waterview Corp.

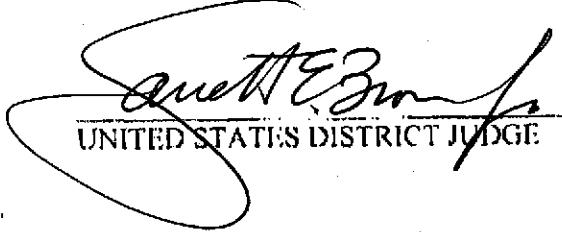
Center, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey, 07054, and shall reference this civil action by case name and civil action number in the communications.

XXI. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

XXII. No sooner than five (5) years after entry of this Decree, Defendants may petition this Court for an order dissolving the Decree. If Defendants have maintained to FDA's satisfaction a state of continuous compliance with this Decree, the Act, and all applicable regulations during the five (5) years preceding Defendants' petition, the Government will not oppose such petition.

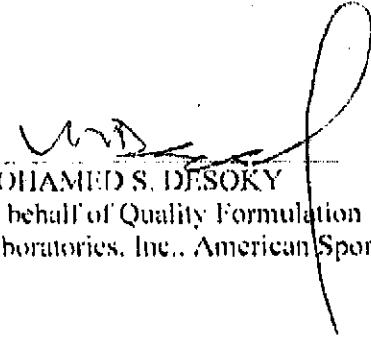
SO ORDERED:

Dated this 16 th day of March, 2010.

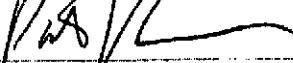
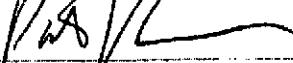

UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of this Decree.

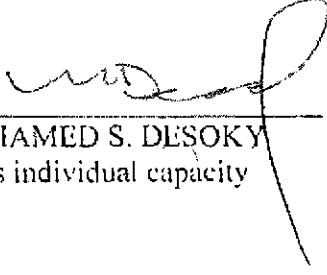
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on behalf of Quality Formulation
Laboratories, Inc., American Sports

For Plaintiff:


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United States Attorney
By: 
PATRICK R. RUNKLE
Trial Attorney
Office of Consumer Litigation

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MOHAMED S. DESOKY
in his individual capacity

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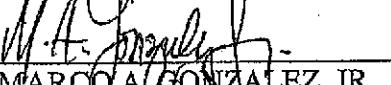
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